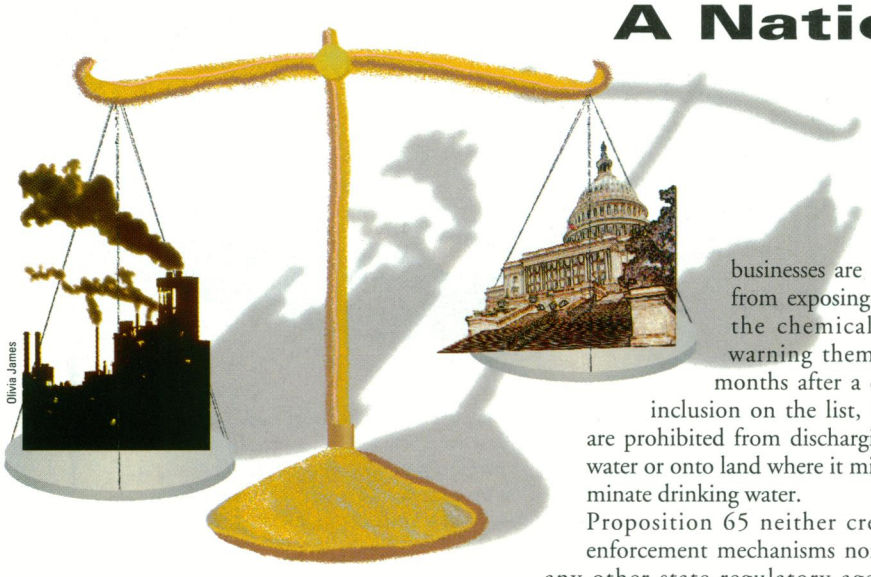
A National Proposition 65?



Olivia James

As the 104th Congress debates several bills aimed at reforming the methods by which federal agencies assess and regulate chemical risks, a California law might seem a likely model for broader emulation. Supporters of California's Safe Drinking Water and Toxic Enforcement Act of 1986 tout the law as a blueprint for effective assessment and management of toxic chemicals. The law, which continues to be known by its ballot name of Proposition 65, has enabled the creation of specific risk-based standards for a list of chemicals that is vastly larger than any comparable federal inventory. Proposition 65's advocates say the law achieves results by placing the burden of proof of safety on manufacturers instead of on government regulators, which creates an incentive for rapid compliance instead of delaying tactics. Supporters say Proposition 65 has reduced Californians' overall exposure to carcinogens and reproductive toxicants with minimal bureaucracy or cost to taxpayers.

Essentially, the law requires the governor's office to compile and maintain a list of chemicals that are either carcinogens or reproductive toxicants and to identify levels at which each offers "no significant risk." Carcinogenic compounds are considered to represent no significant risk if their presence falls below a level causing "one excess case of cancer per 100,000 individuals exposed over a 70-year lifetime." For reproductive toxicants, no significant risk is defined as "less than one-thousandth of the no observable effect level." If a chemical's presence falls below these levels, it is exempt from Proposition 65.

Twelve months after a chemical is listed, businesses are prohibited from exposing people to the chemical without warning them. Twenty months after a chemical's inclusion on the list, businesses are prohibited from discharging it into water or onto land where it might contaminate drinking water.

Proposition 65 neither creates new enforcement mechanisms nor relies on any other state regulatory agencies for enforcement authority. Instead, enforcement is statutorily vested in citizens, allowing "any person in the public interest" to bring suit after a 60-day notice. Such plaintiffs may also share in the money collected as penalties—$2,500 per day—for violation of the statute.

The belief that the traditional environmental health regulatory process was inadequate, said William Pease, a professor in the School of Public Health at the University of California at Berkeley and a supporter of Proposition 65 from its inception, was widely shared in California in the 1980s and was the reason Proposition 65 was formulated. "You have to call it a classic expression of toxics populism," he said. "It was during the mid-Reagan years and there was a distrust that government would intervene to protect the public health, a feeling that the government was cutting deals with polluters, and that sort of thing." As David Roe, senior attorney with the Environmental Defense Fund, says, two decades of experience under "some dozen federal statutes requiring risk-based regulation and in some half-dozen different agencies," showed him that "risk assessment as a regulatory tool is excruciatingly expensive, contentious, and slow."

Proposition 65 sought to achieve rapid compliance from industry by devising a fresh approach to the notion of incentive. John Dwyer, a University of California-Berkeley environmental law professor, says that the unique characteristic of Proposition 65 rests in its power to shift the burden of proof. "Under most statutes, the incentives are for the producers to delay, to have more studies, to think about the problem," he said. "It's paralysis by analysis, because all regulatory controls cost money, no matter how sensible they are. Proposition 65, however, says that you're vulnerable to litigation unless you get in there with the agency fast and figure out what is a significant risk level. I think that's had some impact in taking the delay out of the system. In a sense, it bypasses some of the normal administrative process by focusing on the litigation process. You don't see a big administrative agency here."

However, even Proposition 65's staunchest supporters concede that broader application of a Proposition 65-type law nationwide is not likely to happen. At least, not now. "I don't think it's politically viable," Pease said. "Right now, it's clear that a lot of intended use of risk assessment and cost–benefit analysis, like in the Contract with America, is really meant to be an analytical brake on regulatory action."

Still, Proposition 65 contains elements that should be attractive to lawmakers interested in cutting the cost of government. In fact, the Republican Contract with America's stated aversion to the methodology of federal environmental regulation has much in common with Proposition 65.

Pease and Roe refer to the regulatory method of conventional laws as "command and control," because it has the effect of giving industry the incentive to delay compliance as long as possible. They point to this incentive to delay as the key stimulus in the creation of Proposition 65. "The snail's pace of risk assessment has been an important reason that many of its intended constituents have lost faith in it," Roe told President Clinton's Commission on Risk Assessment and Risk Management in February. "Groups concerned about health, safety, and environmental protection are not willing to wait forever for the risk assessment homework to be done and are distressed the public is being used as a perpetual guinea pig for known but unquantified, and therefore uncontrolled, risks."

The Threat of Litigation

When Proposition 65 became law, California businesses responded with unified alarm. As time has gone on and Proposition 65 has become viewed as one of the costs of doing

business in California, the reaction from businesses has become more varied. Some businesses have even used Proposition 65 as a "green marketing" tool, according to Pease.

While the chorus of business opposition to Proposition 65 is not as strong as it was, there is still significant opposition to it. Michele B. Corash, a San Francisco environmental lawyer who represents defendants in Proposition 65 cases, contends that the law "poses a lot of unnecessary costs on the regulated community." Corash, who worked in the EPA general counsel's office during the Carter administration, particularly criticizes a provision of Proposition 65 under which citizen plaintiffs can collect 25% of any penalties levied against defendants. "There's this 'bounty hunter' provision, which is being used exactly in that way. It's being used by people with no interest in the purpose of the statute in order just to line their pockets and bring cases that are frivolous. There are organizations that file hundreds of 60-day notices and demands for eight, ten, twelve thousand dollars—little enough that it's not worth fighting them."

In essence, Corash says, Proposition 65 has created a cottage industry for these plaintiffs. "These cases are not litigated. There is not a single Proposition 65 case that has ever been litigated to judgment on the issue of whether or not there was a risk that required a warning. There has been only one case that has been litigated to judgment and that was simply on the issue of whether the warning on the label was good enough."

In that case, brought by the Environmental Defense Fund against a company for failing to warn consumers of the presence of methylene chloride in its paint stripper, a jury ordered the defendant to pay a judgment of $210,000. According to Ed Weil, an assistant California attorney general, the total settlement amounts received by plaintiffs are not precisely known, "but if I would guess a number, it would probably be about $10 million." Weil estimates that the majority of that figure has come from suits initiated by his office.

Defending a case involving hard science in a local district court is seen as a risky proposition for any manufacturer, Corash said. But more important, she added, are the ancillary costs of being targeted by people using Proposition 65. For instance, if a manufacturer is sued over the contents of a product, any retailer carrying the item can also be liable. Retailers' typical response in that instance, she said, is to remove the product from their shelves or displays. "What happens is, every time there's a case like this, the manufacturers decide that their least expensive thing to do is just to warn—and to settle—because it costs hundreds of thousands of dollars, maybe millions, to litigate a case where there's a scientific issue involved."

Industry criticism of Proposition 65 focuses largely on the law's "guilty until proven innocent" approach, but also extends to the chemical list that enables plaintiff actions. According to Catherine Caraway, senior hazardous materials specialist with the California state EPA's Office of Environmental Health Hazard Assessment, the list is gleaned from several sources: carcinogens identified by the National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC), reproductive toxicants identified by the Occupational Safety and Health Administration (OSHA), and substances of both types identified by an appointed panel of scientists and by other bodies that the panel considers authoritative. The list currently exceeds 500 compounds.

Proposition 65's proponents say that the "no significant risk" levels provide manufacturers a "safe harbor." Industry spokespersons, however, criticize the levels as being far too low. "Basically, they're set at a detectable level," said John M. Hunter, a Sacramento lawyer who serves as consultant to an organization called The Environmental Working Group, whose members include manufacturing associations and individual companies. "So if you detect the compound in your product, you're going to be subject to a warning. And the way they set those numbers is not by a traditional risk assessment method, but rather [by] a review of the literature and the other risk assessments other people have done for a variety of reasons, and then trying to extrapolate those to be applicable in California. It is very imprecise."

The Net Effect

To a certain degree, Proposition 65's defenders agree. But as Roe has pointed out, in the absence of designated levels, the removal of potentially dangerous chemicals from public exposure is a slow process. In an article published in *Economic Development Quarterly* shortly after Proposition 65 was enacted, Roe referred to the passage of the federal Safe Drinking Water Act in 1974, brought about in part by studies that identified more than 100 dangerous chemicals in the New Orleans municipal water supply, and the fact that, 15 years later, regulators had set acceptable exposure standards for only 9 of those chemicals. Experiences with the Toxic Substances Control Act and the Clean Air Act have been similar. "In short," Roe wrote, "lawmakers hand the difficult chore of line-drawing to regulators, and there it stands."

"If you look at the regulation of hazardous air pollutants under the Clean Air Act, we're talking about known human carcinogens like benzene taking as long as 10 years to develop control rules for major sources," said Pease. "In the meantime, people are being exposed. This isn't even treating them like guinea pigs; this is exposing them to a known human leukemogen. That kind of ongoing exposure . . . is exactly what [Proposition] 65 was designed to cut through. And it does it very effectively."

The biggest impact of Proposition 65, Pease said, has been in consumer products that have been reformulated by manufacturers to meet the law's requirements. The law has resulted in the removal of trichloroethylene from paper correction fluid, tetrachloroethylene from spot removers and water repellent, and lead from wine bottles and their foil caps. Paint strippers containing methylene chloride have either been withdrawn from shelves or reformulated, and manufacturers have made lead crystal and china safer by a process that prevents lead from leaching. The second largest impact, Pease said, has been a reduction in releases of listed chemicals into urban airsheds, "including the virtual elimination of some major source category releases for a lot of problem contaminants." One such category is ethylene oxide, used as a fumigant and sterilizer by manufacturers of medical devices and spice packagers. But in other ways, Proposition 65 has revealed its limitations. For instance, multisource air emissions like benzene have largely remained beyond the scope of Proposition 65.

A Plan of Action?

While "command and control" has been slow and ineffective in many ways, there still seems to be a place for it. Although it may not be a panacea for problems involved in traditional risk assessments, Proposition 65 has drawn attention from scientists and policy analysts examining alternatives to national risk reform, including President Clinton's Commission on Risk Assessment and Risk Management. Roe believes the commission is favorably disposed to a Proposition 65-type measure on a national basis. The commission has stated it will make its recommendation in 1996.

John D. Graham, director of the Harvard Center for Risk Analysis, has monitored developments on Capitol Hill and has perceived "a broad consensus in the House and the Senate that risk assessment needs to play a more central role in the regulatory activities of federal agencies—that when agencies take action, it should be based on scientific assessment of risk, ranking of risk when they're setting priorities, and that there's a need to weigh the costs of regulatory actions against the benefits." Proposition 65, however, "has not played any significant role in the national debate about regulatory reform," Graham said, "although you can probably make a reasonable argument that it should."

Graham asserts that one of the attractive features of Proposition 65 is that "it places the technical burdens of risk assessment where they belong and where they can be most com-

petently handled, and that's in the private sector." This placement may also be prudent because, according to Graham, "it seems unlikely that taxpayers are going to make major investments in the risk-assessment capabilities of federal and state agencies."

James D. Wilson, a fellow at the Center for Risk Management, a Washington think-tank, shares Graham's assessment that Proposition 65 might be instructive nationally, specifically as a means of reexamining regulatory incentives to remove the incentive to delay. "If the incentive system were different from the present incentive system, you could get better environmental protection with less money and time," he said. "Part of changing that incentive system involves making the producers and the emitters and so on responsible for a lot of the information . . . that they're not responsible for now." Wilson, a former policy analyst with Monsanto in California, doubts, however, that anything resembling a full-scale federal statute modeled after Proposition 65 could work. Wilson said the EPA has all it needs in the Toxic Substances Control Act to "create incentives for manufacturing industry to identify what the serious problems are and to act on them."

The EPA's latitude in assessing the risk of dangerous substances to which the public is exposed may be narrowed under a bill, HR 9, that stemmed from the Contract with America and passed the House of Representatives by a wide margin. This bill and others being debated in the Senate share the idea of "providing, in their words, the best estimate of the risk," said William A. Farland, director of health and environmental assessment for the EPA in Washington. "The idea is to push risk assessors to be more realistic in their risk information than they apparently were felt to have been, and also require more risk comparisons so that people can understand whether this [particular risk] is a big issue or a small issue."

"In the interest of fairness," Farland continued, "I would say that this is a push to try to improve the process of risk assessment on the one hand, but on the other hand, it's very much an opportunity for the requirements to be placed on the federal government, in this case, to basically bog it down in lots of analysis and not be able to do the regulation."

Assessing the regulatory atmosphere in Washington in April, Pease said, "It's very clear that, at least on the House side, the mind set is that there are no major environmental health problems requiring regulation—certainly not in the arena of toxic substances control, and particularly not for carcinogens. And therefore, setting up a system that even does market-based control on those types of problems is anti-business."

But as Dwyer points out, although Congress may not be receptive to a Proposition 65 model now doesn't mean it won't be later. "You just have to keep the mid-term in mind, and the mid-term is the next 10 years. The question is, does Proposition 65 over the next few years offer some useful things?"

If the next few years are like the last few, California's brainchild of health hazard regulation will spawn no imitators. According to Roe, several states have considered laws resembling Proposition 65, but none have been enacted. Ohio placed a similar initiative on the ballot in 1992, but it was defeated as a result of heavy lobbying by industry, according to Roe.

Still, Proposition 65 has some support. In a report by the Risk Dialogue Group, an ad hoc organization of risk assessment and risk management professionals, Proposition 65 is referred to in recommendations to governmental bodies regarding risk assessment and management. The report touts the law's effectiveness in overcoming "the strong disincentives to cooperation, disclosure, and finality that [federal policy-makers] have learned to take for granted in most risk-based regulatory systems." The report further states, "When all affected parties perceive that decisiveness on risk issues is to their benefit, the risk assessment process can move quickly and be highly productive. . . . The experience of the California Office of Environmental Health Hazard Assessment would be well worth consulting in any consideration of improved incentive structures for the successful use of risk assessment in statutory and regulatory contexts."

Richard Dahl